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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,529	05/31/2000	Colin Collins	023070-111900US	6021

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/06/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/586,529

Applicant(s)

Collins et al.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 20, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4,8 20) ☐ Other:

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DETAILED ACTION

Status of Claims

1. Response to election of species requirement is acknowledged. Upon close review of the claims, however, it was found that the claims subject to election of species requirement are either not further limiting the base claim or are obvious variants. Accordingly, all pending claims, claims 1-23 are addressed in the following Office action.

Information Disclosure Statement

2. Applicants' Information Disclosure Statements, papers # 4,8 have been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

Claim Objections

3. Claims 7-9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a their base claim 1. The descriptors (as opposed to further limitations) present in these claims are not related to method steps I) to iv) as claimed in claim 1, and do not further limit said method steps. Accordingly, claims 7-9 have not been further treated on the merits.

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Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The definition "relationship between the members" (claim 1(iv)) is vague and unclear and one of ordinary skills in the art would not be reasonably appraised of the scope of the invention. Furthermore, similar terms used at the end of claim 1 "difference in observed relationship" and "expected relationship" are also vague and unclear.

Claim Rejections - 35 USC § 102 and 103.

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103[©] and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1,3,11 are rejected under 35 U.S.C. 102(b) as anticipated by Brosch et al. or Maharis et al.

Brosch et al reference teaches plurality of BAC clones with determined terminal sequences. The clones can be used for comparative genomics. Thus, the clones are compared to total genomic DNA from *M. Tuberculosis*, and differences in the locations of certain sequences are identified.

Maharis et al reference teaches the sequence-tagged connector (STC) strategy which comprises generation of BAC-cloned sequence tags, present every 3.3 kb, and end sequencing of each of them. The STC recourse obtained thereby can be used

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to compare with a reference human genome. See abstract, and p. 9743, second paragraph.

It is the Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed by the teaching of the references cited above.

6. Claim 1 is rejected under 35 U.S.C. 103(a) as obvious over Brosch et al. or Maharis et al. and further in view of Alshtul et al. The primary references, which has been discussed above, are used as representative references teaching end sequence, profiling of a library of clones. Having obtained such information, one skilled in the art would obviously be motivated to determine whether said sequences have any physiological relevance, i.e., whether they can be identified in any known collection of polynucleotides, or, even better, in a full known genome. There are numerous computational methods of nucleic acid sequence comparison, BLAST method (described in Alshtul et al) being the best known.

7. Claims 1-23 are rejected under 35 U.S.C. 103(a) as obvious over Brosch et al. or Maharis et al.

If there are any differences between Applicant's claimed methods and that of the prior art, the differences would be appear minor in nature. Although the prior art

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do not teach all specifics of amount and density of clones (as in claims 6,15-18,19-22) or determining their frequency (as in claim 10,13,14), or potential test/reference genome permutations (as in claims 3-5), or executing method using such tools as automated sequencing and computer (as in claims 22,23), it would be conventional and within the skill of the art to determine such parameters and usages as a part of routine optimization which is within the skill in the art to which this invention pertains.

Prior art made of record

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US Patents 5,830,645 and US 6,013,439.

Conclusion.

9. No claims are allowed

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Serial Number: 09/586529

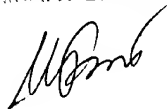
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Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 2, 2002

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

A handwritten signature in dark ink, appearing to read 'MBorin', is written over the printed name and title.